Exhibit 1

PATENT APPLICATION
DOCKET NO. 23625.CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	David Fikstad
SERIAL NO.:	10/764,016
FILING DATE:	01/23/2004
FOR:	PHARMACEUTICAL COMPOSITIONS WITH SYNCHRONIZED SOLUBILIZER RELEASE
ART UNIT:	1614
EXAMINER:	Leslie Royds
DOCKET NO.:	23625.CON

CERTIFICATE OF TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being facsimile transmitted or deposited with the United States Postal Service as First Class Mail, postage prepaid, under 37 C.F.R. § 1.8 on the date indicated below and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Name

June 20, 2006
Date of Deposit

DECLARATION OF MAHESH V. PATEL, DAVID FIKSTAD, SRINIVASAN VENKATESHWARAN, AND CHANDRASHEKAR GILIYAR, AND UNDER 37 C.F.R. § 1.131

Assistant Commissioner of Patent and Trademarks
Washington, D.C. 20231

I, Mahesh V. Patel, declare as follows:

1. I am a named inventor in the above-captioned application and the subject matter described and claimed therein.

2. It is my understanding that various claims in the above-recited patent application have been rejected in view of US Patent No. 6,294,192 (hereinafter "the '192 patent"). It is further my

understanding that the '192 patent was filed on February 26, 1999, and issued on September 25, 2001.

3. I conceived and reduced to practice the invention as described and claimed in the present application (U.S. Serial No. 10/764,016) prior to February 26, 1999 along with Feng-Jing Chen (who is no longer employed with the company and is unavailable). Written descriptions of embodiments according to the independent claims of the present application were recorded on pages of a laboratory notebook dated prior to February 26, 1999. Exhibit 2 is a redacted copy of the above-recited pages showing conception and reduction to practice of pharmaceutical formulations containing a therapeutically effective amount of a drug, a solubilizer, and a release modulator. For example, formulations are shown having a solubilizer (Tween-20, oleic acid), a release modulator (polyvinylpyrrolidone), and a drug (itraconazole).

4. I, David Fikstad, declare that I am a named inventor of the present application and an employee of Lipocine, Inc., and that I agree with, and believe the foregoing statements of Mahesh V. Patel. I also hereby state that I had an obligation to assign to Lipocine Inc. at the time the invention described in the present application was made.

5. I, Srinivasan Venkateshwaran, declare that I am a named inventor of the present application and an employee of Lipocine, Inc., and that I agree with, and believe the foregoing statements of Mahesh V. Patel. I also hereby state that I had an obligation to assign to Lipocine Inc. at the time the invention described in the present application was made.

6. I, Chandrashekar Giliyar, declare that I am a named inventor of the present application and an employee of Lipocine, Inc., and that I agree with, and believe the foregoing statements of Mahesh V. Patel. I also hereby state that I had an obligation to assign to Lipocine Inc.

at the time the invention described in the present application was made.

5. We, Mahesh V. Patel, David Fikstad, Srinivasan Venkateshwaran, and Chandrashekar Giliyar, declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statement may jeopardize the validity of the application or any patent issuing thereon.

DATED this 20th day of June, 2006.

Mahesh V. Patel

6/20/06

David Fikstad

6/20/06

Srinivasan Venkateshwaran

Chandrashekar Giliyar

[redacted]

Itraconazole was weighed (5 or 15 mg) and added to formulation III_{5a}, III_{5b} and III_{5c}. After vigorous shaking and tumbling at 37°C, only $III_{5a\text{-}10}$ and $III_{5c\text{-}10}$, formed clear solution of itraconazole free of suspended particles.

Formulation III_{5a}:		
	glycofurol	0.5 g
	Tween-20	0.3 g
	phosphoric acid	0.1 g
	ethanol	0.2 g
	sodium taurocholate	100 mg
	polyvinylpyrrolidone (PVP 10,000)	saturated by adding 50 mg

$III_{5a\text{-}10}$ contains ~5 mg of itraconazole in ~0.5 ml (~500 mg) of the above composition, makes it ~10 mg/ml.
$III_{5a\text{-}30}$ contains ~15 mg of itraconazole in 0.5 ml (525 mg) of the above composition, makes it ~30 mg/ml.

Formulation III_{5b}:		
	glycofurol	0.5 g
	Tween-20	0.3 g
	phosphoric acid	0.1 g
	ethanol	0.2 g
	sodium taurocholate	100 mg
	polyvinylpyrrolidone (PVP 10,000)	saturated by adding 100 mg

$III_{5b\text{-}10}$ contains ~5 mg of itraconazole in ~0.5 ml (~530 mg) of the above composition, makes it ~10 mg/ml.
$III_{5b\text{-}30}$ contains ~15 mg of itraconazole in 0.5 ml (530 mg) of the above composition, makes it ~30 mg/ml.

Formulation III_{5c}:		
	glycofurol	0.5 g
	Tween-20	0.3 g
	phosphoric acid	0.1 g
	ethanol	0.2 g
	sodium taurocholate	100 mg
	polyvinylpyrrolidone (PVP 360,000)	saturated by adding 25 mg

$III_{5c\text{-}10}$ contains ~5 mg of itraconazole in ~0.5 ml (500 mg) of the above composition, makes it ~10 mg/ml.
$III_{5c\text{-}30}$ contains ~15 mg of itraconazole in 0.5 ml (528 mg) of the above composition, makes it ~30 mg/ml.

[redacted]

Read and Understood By

Signed [redacted] Date Signed [redacted] Date

[redacted]

Phosphoric acid is the cause of PVP not solubilized in the excipient solution

PVP was pre-solubilized in glycofurol at 200 mg/g. 300 mg of the PVP solution, 250 mg of glycofurol, 300 mg of Tween-20 and 100 mg of ethanol was mixed and PVP stayed in solution. Addition of 100 mg of phosphoric acid to the mixture induced the formation of white precipitate from the solution. To avoid the precipitation of PVP induced by phosphoric acid, 200 mg of oleic acid was added to the mixture to replace phosphoric acid. To the phosphoric acid-free excipient solution, 100 mg of sodium taurocholate was added further. At this point, everything stayed in solution and the solution was used to prepare itraconazole formulation.

Formulation III_{e4}:		
	glycofurol	0.5 g
	Tween-20	0.3 g
	oleic acid	0.2 g → ~0.4 g
	ethanol	0.1 g
	sodium taurocholate	100 mg
	polyvinylpyrrolidone (PVP 10,000)	50 mg

~0.1 g H_3PO_4

III_{e4-10} contains ~5 mg of itraconazole in ~0.5 ml (520 mg) of the above composition, makes it ~10 mg/ml.
III_{e4-15} contains ~15 mg of itraconazole in 0.5 ml (520 mg) of the above composition, makes it ~30 mg/ml.

[redacted]

Read and Understood By

Signed [redacted] Date

Signed [redacted] Date